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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/791,061

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Jaime Simon

42801C

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The Dow Chemical Company

P.O. BOX 1967

2040 Dow Center

Midland, MI 48641

EXAMINER

FISHER, ABIGAIL L

ART UNIT

PAPER NUMBER

1616

NOTIFICATION DATE

DELIVERY MODE

11/26/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

FFUIMPC@dow.com

Office Action Summary	Application No. 10/791,061	Applicant(s) SIMON ET AL.	
	Examiner ABIGAIL FISHER	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6 and 7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6 and 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 27 2009 has been entered.

Receipt of Amendments/Remarks filed on December 16 2009 is acknowledged. Claims 1-5 were cancelled. Claims 6-7 were added. Claims 6-7 are pending.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 6 as currently written is vague and indefinite. The claim recites a method comprising administering a water-soluble polyether glycol polymer of a particular formula (shown on page 3 of the claims) which possess a molecular weight from about 5000 to about 750,000. The claim is indefinite as the structure shown on page 3 does not possess a repeating unit; therefore it is unclear how the polymer can have a varying molecular weight as the structure shown on page 3 possesses only one molecular weight. Ultimately, it is unclear if applicants intend to claim the structure shown on page 3 with a single molecular weight or if a varying molecular weight is intended to be claimed and brackets, which represent a repeating unit, were mistakenly not included in the structure. The claim is indefinite as it is unclear what structure of the polyether glycol polymer is intended to be claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.

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3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Holmes-Farley et al. (WO '9505184, cited on PTO Form 1449) in view of Symm et al. (US Patent No. 4056510, cited on PTO Form 1449).

Applicant Claims

The instant application claims a method for decreasing the absorption of phosphate or oxalate from the gastrointestinal tract of an animal which comprises the step of administering a formulation comprising a pharmaceutically acceptable carrier and a water soluble polyether glycol prepared by polymerization of epihalohydrin and derivatizing the polyether backbone of the polymer with ethylenediamine or diethylenetriamine.

**Determination of the Scope and Content of the Prior Art
(MPEP §2141.01)**

Holmes-Farley et al. is directed to phosphate-binding polymers for oral administration. The invention removes phosphate from a patient (i.e. absorbs phosphate) by ion exchange. The composition contains at least one phosphate-binding polymer. The polymers are cross linked with a cross linking agent such as epichlorohydrin (page 2, lines 24-30). An exemplified polymer is poly(DET/EPI) which is poly(diethylenetriamine/epichlorohydrin). This polymer absorbs 2.2 meq/g phosphate (page 10, line 22).

**Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)**

While Holmes-Farley et al. does teach a polymer comprising diethylenetriamine and epichlorohydrin, Holmes-Farley et al. does not teach a polymer with a polyepichlorohydrin backbone derivatized with diethylenetriamine. However, this deficiency is cured Symm et al.

Symm et al. is directed to amine-modified polymers. Symm et al. exemplify preparing an epichlorohydrin polymer which has a molecular weight of about 26,000 (example 1). Then this is derivatized with ethylenediamine (example 1). Polyamine reactants other than ethylenediamine taught include diethylenetriamine (column 4, lines 20-21).

***Finding of Prima Facie Obviousness Rationale and Motivation*
(MPEP §2142-2143)**

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Holmes-Farley et al. and Symm et al. and

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utilize a polymer of epichlorohydrin derivatized with diethylenetriamine or ethylenediamine to absorb phosphate. One of ordinary would have been motivated to utilize these polymers and Holmes-Farley et al. teach utilizing structurally similar polymers (i.e. polymers made of epichlorohydrin and diethylenetriamine) for removing phosphates from the gastrointestinal tract. Therefore, one of ordinary skill in the art would have a reasonable expectation of success as polymers with these components (epichlorohydrin and diethylenetriamine) are known to remove phosphates.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Abigail Fisher
Examiner
Art Unit 1616

AF

/Mina Haghighatian/

Primary Patent Examiner
Art Unit 1616